Cynthia Dwyer: I'd like to officially welcome you to today's keynote presentation to kick off the 2021 NIH Virtual Seminar on program funding and grants administration. My name is Cynthia Dwyer and I'm the coordinator of the seminar. I am so pleased to introduce you today to our moderator and presenter for the session, "Perspectives on extramural research in the era of COVID-19." Your moderator today is Megan Columbus. She's the director of the division of communications and outreach within the NIH office of extramural research. And your presenter today is Dr. Michael Lauer, NIH Deputy Director for Extramural Research. So at this time I would like to turn it over to Megan.

Megan Columbus. Thanks so much, Cynthia. So not only is Dr. Lauer the NIH Deputy Director for Extramural Research, he is also NIH's director of the Office of Extramural Research. That's the office that we work in and that's also the office that's bringing you the seminar today. So I'd like to thank Cynthia for her effort in putting together this seminar and I'd like to tell you just a moment what the Office of Extramural Research does, because while we don't award any grants, what we do provide is the infrastructure by which grants get awarded. We provide the policies and the systems and the procedures. All those things are what our office does and those are the kind of things you're going to learn about throughout this conference today. So with that, I'd like to turn it over to Mike. We'll be answering questions as we can. His presentation is a little bit longer than some, and so if we don't get your questions during this session, we do have a session immediately following called "Open Mike" which is basically an ask me anything, so we'll get your questions there. Thanks so much. Mike?

Michael Lauer: Megan, thank you very much, and I want to first start by taking this opportunity to thank you and Cynthia and your team for absolutely outstanding work in putting this virtual seminar on. We were thrilled with the outcome we had last year and we are very excited to present this virtual seminar to you again this year. So I felt what I would do as kicking this off is to share some perspectives on extramural research, particularly during this rather unusual time of COVID-19. Wow, this has been quite a year! Fiscal year, 2021. On the left is the headline about the Moderna vaccine. This was a vaccine which was developed by NIH funded work and it has a 95 percent success rate in preventing COVID-19. It's an absolute miracle. We went from discovery of the virus to discovery of an effective vaccine within 11 months. Something that has never before happened within biomedical science history. On the right is a headline from just a few weeks ago, that Dr. Francis Collins is stepping down as NIH director. Dr. Collins has had an extraordinarily distinguished tenure. He's been director of the NIH for 12 years. He's done absolutely amazing work. This is a bittersweet time. We're very happy for him as he moves on to the next stage of his career, but we also, of course, are looking forward to a transition that's going to be coming up. By the way, if you haven't seen Dr. Collins' welcome address, it's a 6 minute address, it's absolutely fantastic and I would advise you to take a look at it. So perhaps the biggest question that we face as a biomedical research enterprise right now is whether or not science itself can be trusted. Those of you who have been paying attention to the headlines over the past year and a half as COVID-19 and the science of COVID-19 has unfolded, you've probably noticed concerns about whether or not our experts can be trusted. This is a

fascinating book I read, it's written by Naomi Oreskes who is a professor of the history of science at Harvard University. This book was published in 2019, just before the pandemic, and she asks a fundamental question, which is why should we trust science? And to make a long story short, she identifies three factors that explain why science is something that can be--is an enterprise that can be inherently trusted. The first is consensus. The idea is that science does not occur by means of the acts of individuals. Science occurs because of the acts of communities. And these communities which have different types of expertise get together, they engage in what she calls "empirically-informed dissent" or "empirically-informed debate," and in this way they come up with consensus about what may be right, what may be wrong, what is an advance over what we had before and where we need to move forward. The second is diversity. Now, diversity deals with the idea that if we have only one type of scientist, or one group of scientists, addressing a particular question, they have a fixed perspective, they have a fixed bias. They're not able to see the question from multiple different angles. And it is through our efforts to enhance diversity, all kinds of diversity, that we improve the quality of scientific debate and the improvement of scientific outcome. And then the third is what she refers to as "methodological openness" or flexibility. So what I'm going to do is I'm going to talk about each of these items. I'm going to talk about community, I'm going to talk about diversity, and I'll talk about methodological openness and use that as a frame for why biomedical science is so great and why it can be trusted. If we think about the NIH, we are two communities. We are an intramural research community. NIH itself is an institution with thousands of scientists who work essentially in a large government lab. A highly productive government lab. And then, of course, of great interest to all of you is the extramural research community. We support over 2,600 institutions, over 300,000 people in one way or another. Either Principal Investigators, students, postdocs, staff scientists, technicians, grants administrators, a wide variety of people. We issue awards in every state of the union as well as countries all over the world. We cover a wide swath of research basic translational and clinical and the extramural research program is over 80 percent of our budget. So let's talk about the budget. Here is a high-level look, a very high-level look, at the FY '21 budget. It's about $42 billion of which the largest component goes into an area which I think you all care a great deal about, and that's what we call RPGs, or Research Project Grants. It's about 54 percent of the budget. That includes R01 grants, R21, R03, P01 and so forth. Okay, other areas include the SBIR, this is the Small Business and the Tech Transfer programs. This is about 2.7 percent of the budget. Research centers. This would include CTSAs, cancer centers. Other research, of which probably the most important are what we call K awards, or career development awards. We spend about a billion dollars on training. Training would include fellowship awards as well as the T awards, like the T32 awards. We'll talk a bit more about them a little bit later. Research contracts are roughly 8 percent of our budget. About 11 percent of our budget goes to the intramural program. That's the program that is largely on our campus. Government funded scientists. And then finally, about 5 percent of our budget goes to support overhead. I'm now going to show you a series of plots that describe what's been happening in the NIH sphere and particularly in the sphere of Research Project Grants that, remember, Research Project Grants is the largest component of the NIH budget

since 1998. 1998 was an important year because that was the beginning of what we call the "NIH doubling." Between 1998 and 2003, those are those vertical dotted lines that you see on the left. That was the period of the NIH doubling, when the NIH's budget literally doubled. And if you look at the red line, the red line shows the amount of money that went into NIH funding. We went from about $15 billion to close to $30 billion over a relatively short period of time. Okay, then. 2013, if we go on the right, was a particularly bad year. That was the year that the nominal NIH budget was cut due to a phenomenon on Capital Hill known as "budget sequestration." Then, if you look on the right, now look at that red line. The red line, again, is the NIH budget, now in billions of dollars. We went from about $30 billion a year in 2015 to $42 billion a year in 2020, 2021. And actually even that is an underestimate because we received additional funds, supplementals, through COVID. So we have seen a dramatic increase in the NIH budget over the last 5 years. The top line, which is the green line, shows the percentage of money that is going into our research product grants. And again, I'm guessing these are the kinds of grants that are of most interest to you. Back in 1998 it was 55 percent. It went down a little bit. And now back in 2020 we're back up to 55 percent. The blue line on the bottom shows the total amount of money which is going into Research Project Grants. That went from about $8 billion in 1998 to about $22, $23 billion in 2020. This shows the unique number of research project awards we have given over time. So again on the left is 1998, on the right is 2020. The two dotted lines on the left represent the period of time which was the NIH doubling, and then the dotted line on the right is 2013 which was that particularly bad year. All right, so the top line shows the number of unique Research Project Grant awards that we have given, and this has increased from about 24,000--now by the way, these are all awards, both competing and noncompeting awards. So this has gone from 24,000 back in 1998 to maybe about 36,000 back in 2004, 2005, then there was this period of time from 2005 to about 2015 which, as you recall, the NIH budget was rather flat. In fact, the NIH budget was effectively decreasing because of the erosive effects of inflation. So the number of awards that we were giving actually went down. Since 2015 there has been a dramatic increase in the number of RPG awards and we are now giving more Research Project Grant awards than we ever have. Now, the red line on the bottom shows the number of unique Principal Investigators. So that went from about maybe 20,000 back in 1998 to maybe about 27,000 during the period of the stagnation, but look what's happened over the last 5 years. There's been a substantial increase from about 27,000 to 35,000 unique people who are Principal Investigators in at least one Research Project Grant is the R01, or the RO1 . This is probably about 3/4 of the Research Project Grants that we give. So again, on the left we have 1998. These are the number of awards, went from about 22,000 to about close to 31,000 during the time of the doubling. Then, when the doubling ended until 2013 there was a steady decline in the number of R01 grants that we were funding. It researched a nadir, a bottom, in 2015 and since 2015 the number of unique R01 awards, both competing and noncompeting that we are supporting, has dramatically increased and it's essentially back to where we were by the end of the doubling. Okay. Now I'm going to focus on our workforce. I've given you some information about our budget. I've given you information about grants. Now I want to show you what's been happening with our workforce. So one way

we can think about the workforce is by what stage of a career a person is in. Are they in their early, mid, or late career? So the red line shows the proportion of our RPG investigators who are early career. You can see that from 1998 to about 2009, that proportion steadily declined. The green line shows the proportion of our investigators who we call late career and that's age 60 and up. The red line, by the way, early career, is about less than age 45 and then mid career would be everybody else. And you can see that there were these trends whereby early career investigators were going down, late career investigators were going up. Over the last 5 years these trends have stabilized so that we have roughly equivalent proportions every year. We don't think that this is an accident. We think this may be related to a number of policies that we put in place, particularly to nurture early career investigators. Here we show data by gender. The blue line on the top shows the proportion of RPG scientists, Principal Investigators who are men and the red line on the bottom are those who are women. There has been a steady increase in the proportion of RPG PIs who are women, from about 20 something percent to about 34 percent or 35 percent, however we are still way below parity and to put this in perspective, over 50 percent of K awardees, or career development awardees, are women. This shows data by race. The purple line on the top is the proportion of RPG Principal Investigators who are White. That has declined from about 82 percent back in 1998 to about 67 percent in 2020. The reddish line shows the proportion who identify themselves as Asian. That's gone from about 10 percent to 22 percent. The teal line with the squares shows situations where we don't know. Not everybody discloses their demographic to us. That is completely optional. About 10 percent don't. And then the green line on the bottom shows the proportion who are Black. That number has been running around 2 percent and has continued to be fairly low. Now, a high priority for NIH has been funding early career investigators. One way we do this is by supporting them on R01 grants or what we call R01 equivalent grants. This shows the number of early stage Investigators who are funded on an R01 grant in any given year. An Early Stage Investigator is somebody who is within 10 years of their terminal research degree or the end of their clinical training. So back around 1998 we were funding about 1,000 a year. Look what happened in 2013. That's that bottoming out there. That was the bad year, the year of sequestration. We went to funding less than 600 Early Stage Investigators in R01s that year. Since then, there has been a steady and rather marked increase. In 2020 we supported 4,112 Early Stage Investigators on R01 equivalents, and while I don't have the 2021 final data, it's at least that many, it looks like, for 2021. Now, it is important to point out that the NIH system is a competitive one. And in fact some people have described it as a hypercompetitive one. It is not easy to get an NIH grant. So now here what I'm going to show you are some numbers, or data, that reflect our competition. The red line shows the number of unique Research Project Grant applications we have received. You can see that during the period of the doubling on the left, it increased rather dramatically from about maybe 25,000 in 1998 to approaching 50,000 by 2006. We're now running a steady plateau of about 55,000 grant applications per year. Now, even with the new, increased budget, the number of new, competing awards that we can support every year is limited. So that's the green line on the bottom showing the number of unique awards. That's increased from about 9,000 to about 11,000. So there has been a substantial

increase in the number of unique awards, but even so our success rate, which is the proportion of applications that get funded, our success rate is still quite low. It's running around 20 percent. This is a very competitive system. It's very competitive for everyone and it continues to be a lot more competitive than it was during the time of the NIH doubling. During the NIH doubling, the success rate was running around 30 percent or even a little bit higher. It got as low as 16 to 17 percent in 2013. It's now running around 20 to 21 percent. Still a very competitive system. Okay. Now, another way of thinking about this is instead of focusing on applications we can focus on Principal Investigators. We can focus on people. So here, the red line shows the number of unique Principal Investigators who are submitting at least one competitive application each year. That has increased from 20,000 back in 1998 to about 45,000, not quite, in 2020. The line on the bottom shows the number of unique Principal Investigators who received at least one competing award in a given year. That's increased from about 9,000 to say about 13,000 or 14,000. And so the blue line shows what we call the funding rate. So the funding rate is a person based measure. It shows the proportion of Principal Investigators who have submitted at least one grant in a given year, one competing application, who get at least one award. That funding rate was as low as 22 percent or 23 percent back in 2013. It's now running around 29 to 30 percent. Still, no matter how you cut this, this is a highly competitive system. So in summary, we have seen, particularly over the last 5 years, an increase in the number of awards and awardees, an increased number of Early Stage Investigators, and an increased proportion of women, but still well below parity, a persistent low proportion of Black investigators and we are seeing increased success in funding rates despite more applications coming in and more applicants, but nonetheless, the system is still highly hypercompetitive. All right. Now I'm going to totally switch gears and I want to talk about the stresses that are facing our community and particularly the majority of our community who are not engaged in COVID-19 research. These were some headlines that came out very shortly after the pandemic started. Medical research being locked down, "COVID-19 has shuttered labs, putting a generation of researchers at risk." Another big stress, which we all are quite aware of, is an increasing sensitivity and awareness of structural racism throughout our society as well as, of course, the impact of structural racism within our own enterprise. Dr. Collins, the NIH Director, issued this statement, "To those individuals in the biomedical research enterprise who have endured disadvantages due to structural racism, I am truly sorry. NIH is committed to instituting new ways to support diversity, equity, inclusion, and identifying and dismantling any policies and practices at our own agency that may harm our workforce and our science." Well, part of our efforts, and this goes back to last year and I'm guessing that maybe many of you participated in this and I want to thank you, is that we issued a survey to the extramural research community. This went out in October, November of last year. We received responses from 45,000 researchers. Earlier this year we had an opportunity then to take a look at the data. We posted high-level findings on our website in March and we are continuing to analyze those data and more will be coming. But these were our main, high-level findings. One is that a majority of researchers, 55 percent, feel that the pandemic is having a negative impact on their career trajectory. About 2/3 feel that societal and political events are negatively affecting their mental health, and about 80 percent

feel that the pandemic is having an adverse effect on their research productivity. So now I want to focus on some data where we look at, people sense that the pandemic is having a negative impact on their career trajectory. Here, we look at career stage. On the left we have postdoc fellows, or residents, people who are in the earliest stages of their career. On the right we have people who are well established researchers and we see this steady gradient, whereby the earlier one is in one's career, the more worried they are that the pandemic is having a negative impact on their career trajectory. So only 34 percent of well established researches felt that they were at risk for a negative trajectory, whereas close to 70 percent of the earliest career people were worried. Here we look at data according to the kind of research that's being done. Sixty-one percent of people who work in laboratories were concerned about their career trajectory as compared to 45 percent of those who are doing public health research. Here, I think the point is that across the board there's a high degree of worry, but not surprisingly people who work in laboratories have greater concerns. And here we break the data down by race and gender. The people who are most concerned about how the pandemic was affecting their career trajectory were Asians and followed by others. So 67 percent of Asians, both men and women, 62 percent of Asian women and 67 percent of Asian men were worried about the impact of the pandemic on their career trajectory. Now, we collected a massive amount of data. Over 150 variables. And so we looked at what were the variables that were most correlated with a higher risk or a higher likelihood of anticipating a negative career trajectory. The biggest one was ability to apply for grants, and what that means is a concern about generating enough preliminary data to put together a strong grant application. Other concerns include progress towards promotion and tenure, reduced access to laboratories, and caretaking responsibilities. We did break down this data and as one might expect, women who were responsible for young children noticed the highest likelihood that the pandemic was negatively affecting their career trajectory. NIH has strong priorities for Early Career Investigators. I think one of the messages of the survey is that Early Career Investigators are among those who are most worried about what's going to happen. We have instituted a number of flexibilities including no-cost extensions, including second no-cost extensions. In some cases, funded extensions for select F and K awards and eligibility extensions, for example, for Early Stage Investigators. We've offered Early Stage Investigator extensions have doubled from about 500 to 1,000. Leniency on late applications. And another step that we've taken since the pandemic started is that we allow preliminary data to be given post-submission. This is something that we used to never allow, but we now do allow it and a very large proportion of our applicants are taking advantage of that. This is a big deal, which is that we provide assistance for childcare. We started this last March on Fellowship Awards, F awards, as part of the NRSA training program. We allow $2,500 per year per fellow to defray childcare costs and we announced earlier this fiscal year, maybe about a month ago or maybe a little less, plans for T awardees and we will now allow people on T awards to also get up to $2,500 per year per trainee to defray childcare costs. All right, next I want to switch to a topic which is a bit more difficult, and that's to talk about integrity. In order for the enterprise to be trustworthy--remember, this is one of the big questions, do we have a trustworthy enterprise? We have to run our enterprise with integrity.

This was an article that came out early in the pandemic. There were questions about whether or not the data here were true. I'm happy to say NIH was not involved with this study, but we were involved in some other problems. This was a very high profile paper that came out in 2006 from Duke University that suggested that one could identify which patients were going to benefit from treatment with chemotherapy of certain kinds of cancer, and it turned out it wasn't true. It turned out that those data were fraudulent. Now, that problem as well as other problems at Duke University, with multiple episodes of misconduct and integrity violations led to a $112.5 million settlement in 2018. The president of Duke University pointed out that this was "a difficult moment. It demonstrates the devastating impact of research fraud and reinforces the need for all of us to have a focused commitment on promoting research integrity and accountability." In order for our enterprise to be trustworthy, we have to promote integrity and accountability. And that's a responsibility that falls on all of us. There are consequences. I mentioned, of course, the very large, greater than $100 million settlement at Duke University. This one was just announced a couple of months ago, a scientist who had included false data in their grant application and that led to a $215,000 settlement with the Department of Justice. This was an even more serious case in which a scientist lied on a number of grant applications about research support that he was receiving from elsewhere and this led to a 37-month prison sentence as well as $3.4 million in restitution. This was a very concerning case because had NIH known about the other kinds of research support and other financial interests that this scientist had, we would not have funded those grants. The harms of scientific misconduct are real. This was a notorious paper on the left that was published in The Lancet in 1998 that suggested that routinely given vaccines in children could cause autism. This paper has been disproven over and over and over again, but nonetheless it has contributed to a sense of vaccine hesitancy or vaccine doubt and the consequences are real. We're seeing it now in that not everybody in our population have been vaccinated for COVID. We've seen outbreaks of measles. When I went to medical school, I was taught that I would never see a case of measles because with the measles vaccine we had essentially eradicated the disease, but when the vaccine stopped, the virus came back. Another big area of concern is sexual harassment in science. We have now addressed hundreds of cases of possible harassment and discrimination within the workplace. We work with institutions to address those and we now require institutions, we tell institutions that it is expected for them to let us know about safety or work environment concerns if there's a change in Principal Investigators or key personnel. The NIH actually constituted a working group in 2019. This working group put out a report in late 2019 on changing the culture to end sexual harassment. There were a number of themes there and one particular theme that is-- well, these themes are relevant to our discussion today. Transparency and accountability in dealing with professional misconduct, including sexual harassment, mechanisms for restorative justice. That's something that we're continuing to work on. Fostering safe, diverse and inclusive environments and system-wide change. And we do have .. . one of the recommendations from that working group was that we develop a process to address professional misconduct, including sexual harassment, in as serious a way as we address research misconduct. Research misconduct means falsification, fabrication or plagiarism. So we have done that. We address all

kinds of integrity threats including research misconduct, harassment, discrimination, hostile work environment, retaliation, possible grant fraud, foreign interference, peer review violations. We have handled 100s of these and regarding professional misconduct or harassment, we've now, over the last few years, addressed over 390 cases. We have a number of ways in which we can receive complains. So we do not only receive complaints from institutions. We can also receive complaints through our mailbox and most importantly through our web forum and we get a number of these complaints and deal with them. All right. So the last thing I want to do is come back to our original question. Our original question is why should we trust science? So, one is that we have a community and expertise that through a process of empirically informed dissent we are able to come up with consensus and an important part of this community being able to work well is that it works with highest levels of integrity, transparency, and honesty. The second is that we do all we can to enhance diversity within our scientific workforce. All kinds of diversity, and this is important for us to overcome shared biases and allow for multiple perspectives addressing complex questions. And then the last thing that I want to talk about very briefly is something that Dr. Oreskes brought up, which is the idea of methodological openness and flexibility. And that is that we are transparent about the way we do our science. So NIH is now embarking on what we consider to be a major initiative. And that is our policy for data management and sharing. We announced this policy about a year ago in October of 2020. We will be implementing the policy in about a year from now. The policy will apply for applications coming in in January of 2023. Essentially, what the policy says is that all grant applications that involve data will have to include a data management and sharing plan. So there will have to be a plan in which the investigators and the institution will describe how they will manage data and how they will share data. The default is that data will be shared. There's a lot more to this. What constitutes adequate data management, what kind of repositories data should be shared in, there's quite a bit there. But this is something that we are working on and we ask you to take a look and learn more about what we're doing. We're going about this in a deliberative way. So we've gone two years from the time that the policy was announced to the time that it is being implemented so that we can develop a policy and also work on our outreach. And I think the statement here is really important. The extraordinary effort to speed the development of treatments and vaccines in response to the COVID-19 pandemic has put into sharp relief the need for the global scientific community to share scientific data openly. So we are addressing this through our policy and it will establish the baseline expectation that data sharing is a fundamental component of the research process. Now, this is so important that it was explicitly addressed by Congress. Part of the reason why we're able to implement this policy is because of a provision in the 21st Century Cures Act, passed in late 2016, that gives the NIH Director the authority to require data sharing for all NIH awards. And this is the way in which we're implementing that component of the law. So, closing thoughts here. We are part of a community. Our community is growing. We are seeing, particularly with the increased budgets over the past 5 years, an increasing number of awards, an increasing number of awardees, an increasing number of early career awardees. We are very grateful to the Congress for the strong bipartisan support. We are very grateful to the community at large and to the

American public for their strong interest and support for government funded biomedical research. So our community is growing. At the same time our community is stressed. Our community has been stressed for a long time because we operate in a competitive environment. Some say a hypercompetitive environment. So those stressors have been going on for quite a while and continue. On top of that we've had the ongoing effects of COVID-19, the disruptive effects that it has had on all of us and our workforce, and those disruptive effects are not felt equally. There are certain parts of our community that are feeling the disruptive effects to a greater degree. There's been quite a bit written about it and we've also developed some insights, based on our own data, which we thank you for responding to our surveys. We are dealing with, in the society at large, with structural racism which also affects our community as well, and there are a number of efforts at NIH to enhance the diversity of our workforce. Our goal is to make sure that science will be trusted. And in order for us to enhance that and assure that it important that we operate within an environment of transparency and credibility. An environment, a research enterprise that operates without integrity will lose all credibility and we are also working on enhancing the general openness of our community through the data management and sharing policy. I want to thank you again for joining this virtual seminar. There is so much that is going on and we hope that you will take advantage of the many offerings that we have and that you enjoy this seminar and find this seminar interesting and informative. Thank you.

Megan Columbus: Could we get a few questions in before you leave, Mike?

Michael Lauer: Yes, yes.

Megan Columbus: All right, I think we have 4 minutes. So let's see what we can do. Some of the questions that we've gotten here definitely can be addressed in Open Mike, more about demographics and other things. But there's a question here, has ARPA-H been funded?

Michael Lauer: No, that's a great question. So ARPA-H right now is being discussed on Capital Hill but it is not a reality, I hope to say, yet. And exactly when it will be funded, how much will be funded, what exactly it's going to look like is right now in the hands of Congress.

Megan Columbus: And when we're looking at NIH budget increases, do you expect there to be commensurate increases on the limitations of allowable budgets in FOAs and funding opportunities?

Michael Lauer: So we do expect that in some cases there will be more FOAs and funding opportunities, in some cases directed by Congress. An example of that might be Alzheimer's or maternal mortality. And we also expect to see that there will hopefully be increases in monies available for general Investigator initiated grants. But right now, our budget situation for FY '22 is still undefined. We are not operating on a continuing resolution and where we're going to be, we don't know.

Megan Columbus: Great. We do have a few questions on Hispanic investigators. We're not seeing the data on Hispanic investigators and awards?

Michael Lauer: We do have data on Hispanic investigators, it's approximately 5 percent, but I would point out that this is where we have a problem with what we call "data missingness." So one of the questions that we asked people when they registered in eRA comments, we do ask them if they're willing to tell us about their demographic background. For ethnicity we have about a 15 percent missingness rate, so that makes those data a bit more difficult to interpret, whereas for example, for gender it's only about 2 percent missingness.

Megan Columbus: In data sharing, can you talk a little bit about how intellectual property is maintained? And I do know that we have sessions on data sharing if that answer is too long.

Michael Lauer: Yes, there will be sessions on data sharing and of course we do respect issues related to IP. There will also be of course issues related to Small Business Grants, and so that's the reason why we're not saying "you must do X for absolutely everything." That's why we're asking for management and sharing plans and in some cases the plans may say that our ability to share data will be limited because of X, Y and Z. That will then lead to a dialogue with NIH about that.

Megan Columbus: And I think that I don't see any other questions that are short enough that we're going to be able to answer them in the last 1 minute that we have here. Although, I do have a number of questions here on modular budget. So do you expect the increase in budget to raise the modular cap at all?

Michael Lauer: If I were a betting person I would say no.

Megan Columbus: Yeah. And so with that I really want to encourage, I want to thank everybody for showing up. I want to encourage folks who would like to speak more with Mike about this to join the next session on Open Mike. If you are new, however, you might do better going to some of the sessions on fundamentals and the grant process so that you can understand what you're getting into. With that, I'd like to thank you very much for joining us. This session will be recorded, it will be made available within about 24 hours. The presentation slides will also be made available. I think this is one of the few sessions where the slides are not made available ahead of time. And if you like this session let us know. For all of our sessions there's a feedback form right on the page where you got to join this session from, so please let us know and when you finish the conference we really want to hear from you how it's going, how it went. Drop by the general information booth, let us know how it's going because we like to hear from you. Enjoy your sessions! Thank you so much.

Michael Lauer: Thank you!